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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,868	03/10/2004	James L. Hartley	0942.285000K/BJD/JKM	2652
26111	7590	01/03/2006		
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/796,868	Applicant(s) HARTLEY ET AL	
	Examiner Nancy T. Vogel	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/13/05.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-16, 18, 21-35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-16, 18, 21-35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/13/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2-16, 18, 21-35 and 37 are pending in the case.

Receipt of an Information Disclosure Statement on 10/13/05 is acknowledged.

Reference crossed through are Office actions of pending application, and unpolished US Patent Applications, which were considered but would not be appropriate for printing on the face of the patent.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/05 has been entered.

The indicated allowability of claims 2-16, 18, 21-35, 37 is withdrawn in view of the rejection below:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

Art Unit: 1636

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-6, 8-13, 15, 16, 18, 21-25, 27-32, 34 and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 14 and 45-47 of U.S. Patent No. 6,720,140. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2-6, 8-16, 18, 21-25 and 27-35 and 37 recite compositions and kits that are generic to all that is recited in claims 5, 14, and 45-49 of US Patent No. 6,720,140. That is, claims 5, 14 and 45-49 of '140 fall entirely within the scope of claims 2-6, 8-16, 18, 21-25 and 27-35. Specifically, the claims of the '140 disclose the same composition or kit or methods using said composition or kit, as that recited in the instant application, i.e. comprising at least two isolated recombination proteins, at least one first nucleic acid molecule ("Insert Donor DNA molecule") comprising a first recombination site and a second recombination site wherein said first and second recombination sites do not recombine with each other, and at least one second nucleic acid molecule ("Vector Donor DNA molecule") comprising a first recombination site and a second recombination site wherein said first and second recombination sites does not recombine with each other. It is noted that claim 46, which is dependent on claim 45,

recites "at least one recombination protein is selected from the group consisting of Int, IHF, Xis and Cre" and therefore, two different recombination proteins are encompassed. It is noted that the instant claims 3-6 recite that the first and second nucleic acid molecules are circular or linear; the conflicting claims recite "Insert Donor DNA molecule" and "Vector Donor DNA molecule", which are known in the art and further, disclosed in the specification of '140 as linear or circular (see col. 5). It is noted that instant claims 8-16 and 27-35 recite particular recombination proteins, or organisms from which said recombination proteins originate, and the conflicting claims 46-49 of '140 recite the same recombination proteins. While claims 5, 14 and 45-49 of '140 recite that the second nucleic acid comprises a repression cassette encoding a repressor and a selectable marker that is repressed by the repressor, the claims of the instant application are generic to this embodiment and therefore, the instant claims are obvious over the claims 5, 14, and 45-49 in the conflicting patent '140.

Claims 2-6, 8-13, 14, 15, 16, 18, 21-25, 27-32, 33 34 and 35 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 14 and 45-49 of Hartley et al., U.S. Patent No. 6,720,140 in view of Baum et al. (J. Bacteriol., 176 (10):2835-2845, 1994).

Hartley et al is cited for the reasons set forth in the above rejection.

The difference between the reference and the claims is that in the claims, at least one of the recombination proteins is encoded by *B. thuringiensis*.

However, Baum et al. disclose recombination proteins encoded by *B. thuringiensis* and their function as site specific recombinases (see abstract and page 2835, first and second column).

It would have been obvious to one of ordinary skill to have utilized known recombination proteins encoded by *B. thuringiensis*, as disclosed by Baum et al., in the compositions disclosed by Hartley et al., since both references disclose methods of manipulating DNA structure using site specific recombination proteins. One would have been motivated to use *B. thuringiensis* recombination proteins since Hartley et al. disclose that any recombination protein may be used, and since Baum et al. disclose such proteins from a known and useful bacterial species, *B. thuringiensis*. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 2-13, 15, 16, 18, 21-32, 34, 35 and 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 14, and 45-49 of Hartley et al. (U.S. Patent No. 6,720,140) in view of Savakis et al. (US Patent 6,225,121).

Hartley et al. is cited for the reasons set forth above.

The difference between the reference and the instant claims is that the second nucleic acid molecule comprises at least one toxic gene and at least one selectable marker on different nucleic acid segments, separated by at least one recombination site.

However, Savakis et al. disclose vectors comprising a toxic gene and a selectable marker gene, separated by a recombination site, and the usefulness of these components in selection procedures in genetic recombination systems (see columns 7, 8, 10 and 17-20).

It would have been obvious to one of ordinary skill in the art to have combined the teachings of Hartley et al. and Savakis et al., since both references are concerned with compositions for genetic recombination, including selecting for recombination events. One would have been motivated to have done so by the desire to select for recombination events, using known selection systems comprising selectable markers and toxic genes, as disclosed by the references. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

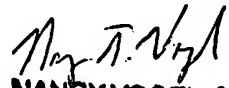
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NANCY VOGEL, Ph.D.
PATENT EXAMINER

ntv
December 26, 2005